

## § 1313.01

- 1313.53 Waiver of modification of rules.
- 1313.54 Request for hearing.
- 1313.55 Burden of proof.
- 1313.56 Time and place of hearing.
- 1313.57 Final order.

AUTHORITY: 21 U.S.C. 802, 830, 871(b), 971.

SOURCE: 54 FR 31665, Aug. 1, 1989, unless otherwise noted.

### § 1313.01 Scope.

Procedures governing the importation, exportation, transshipment and in-transit shipment of listed chemicals pursuant to section 1018 of the Act (21 U.S.C. 971) are governed generally by that section and specifically by the sections of this part.

[54 FR 31665, Aug. 1, 1989, as amended at 60 FR 32465, June 22, 1995]

### § 1313.02 Definitions.

(a) The term *chemical export* means transferring ownership or control, or the sending or taking of threshold quantities of listed chemicals out of the United States (whether or not such sending or taking out constitutes an exportation within the meaning of the Customs and related laws of the United States).

(b) The term *chemical exporter* is a regulated person who, as the principal party in interest in the export transaction, has the power and responsibility for determining and controlling the sending of the listed chemical out of the United States.

(c) The term *regulated person* means any individual, corporation, partnership, association, or other legal entity who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine, or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine.

(d) The term *regulated transaction* means:

(1) A distribution, receipt, sale, importation, exportation, or international transaction of a listed chemical, or if the Administrator establishes a threshold amount for a specific listed chemical, a threshold amount as determined by the Administrator, which includes a cumulative threshold amount for multiple trans-

## 21 CFR Ch. II (4–1–96 Edition)

actions, of a listed chemical, except that such term does not include:

(i) A domestic lawful distribution in the usual course of business between agents or employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person;

(ii) A delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this paragraph does not relieve a distributor, importer, or exporter from compliance with this part or parts 1309 and 1310 of this chapter;

(iii) Any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Administrator as excluded from this definition as unnecessary for enforcement of the Act;

(iv) Any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act unless)—

(A) The drug contains ephedrine or its salts, optical isomers, or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient (for purposes of this paragraph, the term “therapeutically insignificant quantities” shall apply if the product formulation (i.e., the qualitative and quantitative composition of active ingredients within the product) is not listed in *American Pharmaceutical Association (Apha) Handbook of Nonprescription Drugs; Drug Facts and Comparisons* (published by Wolters Kluwer Company); or *USP DI* (published by authority of the United States Pharmacopeial Convention, Inc.); or the product is not listed in